

EXHIBIT 1

DECLARATION OF DR. JÜRGEN KLEINSCHMIDT UNDER 37 C.F.R. § 1.132



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Kern et al.	Confirmation No.: 4876
Serial No.: 08/637,752	Art Unit: 1648
Filed: July 20, 2001	Examiner: Mosher, M
For: ADENO-ASSOCIATED VIRUS - ITS DIAGNOSTIC USE WITH EARLY ABORTION	Attorney Docket No: 8484-013-999

DECLARATION OF DR. JÜRGEN KLEINSCHMIDT UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Jürgen Kleinschmidt, declare and state:

1. That I am an co-inventor of the above named subject matter.
2. That samples of a hybridoma cell line, termed A1, producing monoclonal antibodies, were deposited with the DSMZ - DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmGH, Mascheroder Weg 1b, D-38124 Braunschweig, Germany, under accession number DSM ACC2195 on October 13, 1994. The samples have been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.
3. That samples of a hybridoma cell line, termed A69, producing monoclonal antibodies, were deposited with the DSMZ - DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmGH, Mascheroder Weg 1b, D-38124 Braunschweig, Germany, under accession number DSM ACC2196 on October 13, 1994. The samples have been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

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4. That samples of a hybridoma cell line, termed B1, producing monoclonal antibodies, were deposited with the DSMZ - DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmGH, Mascheroder Weg 1b, D-38124 Braunschweig, Germany, under accession number DSM ACC2197 on October 13, 1994. The samples have been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

5. That samples of a hybridoma cell line, termed A20, producing monoclonal antibodies, were deposited with the DSMZ - DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmGH, Mascheroder Weg 1b, D-38124 Braunschweig, Germany, under accession number DSM ACC2194 on October 13, 1994. The samples have been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

6. In addition to there being no restrictions on the availability, to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. §122, of the deposited cell lines during the pendency of the patent application, any and all restrictions on the availability to the public of the deposited samples referred to in paragraph 2, 3, 4, or 5 will be irrevocably removed when a U.S. Patent based upon the captioned application is granted.

7. I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the captioned application or any patent issuing thereon.

28.08.2003

Date

Jörg Kleinschmidt

Dr. Jürgen Kleinschmidt



EXHIBIT 2

SECOND DECLARATION OF DR. JÜRGEN KLEINSCHMIDT
UNDER 37 C.F.R. § 1.132



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Kern et al.

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For: ADENO-ASSOCIATED VIRUS -
ITS DIAGNOSTIC USE WITH
EARLY ABORTION

Attorney Docket No: 8484-013-999

SECOND DECLARATION OF DR. JÜRGEN KLEINSCHMIDT
UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Jürgen Kleinschmidt, declare and state:

1. That I reside at Weihwiesenweg 5, Bammental, Germany, and am presently employed by the Deutsches Krebsforschungszentrum (German Cancer Research Center), Heidelberg, Germany.
2. That I am a co-inventor of the subject matter of the above named patent application, which is the national phase filing of the Application No. PCT/EP94/03564, which was filed with the Patent Cooperation Treaty on October 28, 1994, and is entitled to priority of European Patent Application 93117452.8, filed October 23, 1993.
3. That I am a co-author with Michael Ruffing and Hanswalter Zentgraf of the following report published by the American Society for Microbiology: Michael Ruffing, Hanswalter Zentgraf, and Jürgen A. Kleinschmidt (December 1992) *Journal of Virology*, volume 66, issue no. 12, pages 6922-6930 ("Ruffing *et al.*").

4. That I am the sole inventor of the subject matter described under the heading "Preparation of anti-VP3 serum" that is described within the first full paragraph in the report by Ruffing *et al.* at page 6924, left column. Michael Ruffing, a member of my laboratory, helped produce the anti-sera against AAV type 2 VP3 at my direction and guidance.

5. That Hanswalter Zentgraf did not contribute to the production of anti-AAV type 2 VP3 antiserum as described within the first full paragraph in the report by Ruffing *et al.* at page 6924, left column.

6. That I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the captioned application or any patent issuing thereon.

25.09.2003

Date

J. Kleinschmidt

Dr. Jürgen Kleinschmidt